

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVO NORDISK A/S,

Plaintiff,

v.

SANOFI-AVENTIS, AVENTIS
PHARMACEUTICALS INC., and AVENTIS
PHARMA DEUTSCHLAND GMBH,

Defendants.

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)
) **REDACTED PUBLIC**
) **VERSION**
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) C.A. No. 05-645-SLR
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**AVENTIS'S REPLY BRIEF IN RESPONSE TO NOVO NORDISK A/S' ANSWERING
BRIEF IN OPPOSITION TO AVENTIS'S MOTION FOR LEAVE TO FILE AN
AMENDED ANSWER AND COUNTERCLAIMS**

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I. AVENTIS HAS GOOD CAUSE TO AMEND THE PLEADINGS

As shown in AVENTIS'S MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR LEAVE TO AMEND ("Supporting Memorandum") and below, the Court should grant AVENTIS'S MOTION FOR LEAVE TO AMEND THE PLEADINGS ("Motion for Leave to Amend"), as Aventis has demonstrated that good cause exists to justify the amendment of the pleadings, and no prejudice to Novo will result from such amendment.

A. Legal Standard

A party may amend its pleading "by leave of court . . . and leave shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). This standard exists to allow parties "an opportunity to test [their] claim[s] on the merits." *Lorenz v. CSX Corp.* 1 F.3d 1406, 1413 (3d Cir. 1993), citing *Foman v. Davis*, 371 U.S. 178, 182 (1962).

B. Novo Will Not Be Prejudiced by Aventis's Second Amended Answer

To show undue prejudice, "the non-moving party must do more than merely claim prejudice; it must show 'that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the . . . amendments been timely.'" *Bechtel v. Robinson*, 886 F.3d 644, 652 (3d Cir. 1989) (citations omitted). Novo has not demonstrated any actual prejudice that will result from the amendment Aventis seeks. The facts concerning the new grounds for inequitable conduct are set forth in detail in the SECOND AMENDED AND CONDENSED ANSWER AND COUNTERCLAIMS ("Second Amended Answer") and are to be developed through the depositions of attorneys and inventors that have already been noticed but not yet taken. Thus, Novo has not been deprived of any opportunity to present facts or evidence.

Novo's reliance on this Court's holding in *Inline Connection Corp. v. AOL Time Warner, Inc.*, 237 F.R.D. 361 (D. Del. 2006), is misplaced. In *Inline*, the defendants' motion for leave to

amend the pleadings was filed more than three years after the original deadline for amendments to the pleadings, and more than two and a half years after the close of fact discovery and the *Markman* hearing.¹ *Id.* at 361-66. Because the *Inline* plaintiff had relied upon the defendants' last answer and counterclaims for **nearly three years**, the Court found that having to formulate new defenses "at this stage of an already lengthy litigation" would constitute prejudice to the plaintiff. *Id.* at 370. Although the Court did not allow claim amendments to add inequitable conduct claims, in the same decision, the *Inline* Court granted leave to amend the pleadings regarding the laches defense. The Court stated that the plaintiffs would not be prejudiced by the proposed laches amendments because the plaintiffs "ha[d] not articulated what additional discovery would be warranted" by the new claims. *Id.* at 366.

Far more apposite to the present case is the holding in *Enzo Life Sciences v. Enzo Biochem, Inc.*, 270 F. Supp. 2d 484, 486 (D. Del. 2003), in which this Court found no prejudice to the plaintiff where the defendant's proposed claim amendments did not necessitate the service of any additional discovery requests. Like the defendants in *Enzo*, Aventis does not plan to serve any additional discovery requests regarding the inequitable conduct issue. Indeed, discovery is closed, and Aventis and Novo have stipulated to the remaining deposition-related activities.² Novo has failed to identify any other issues in this case which would require any additional discovery.

Moreover, Aventis asserted inequitable conduct claims as early as its CONDENSED AND AMENDED ANSWER AND COUNTERCLAIMS ("First Amended Answer"), and, therefore,

¹ Relevant dates to the *Inline* case:

Original deadline for amendments to the pleadings	3/28/2003
Previous answer and counterclaims	5/15/2003
Pleadings filed	4/19/2006
Close of fact discovery	6/27/2006
Markman hearing	8/28/2006

² See D.I. 106.

Novo has been on notice that inequitable conduct would be addressed during the upcoming depositions. Further, any relevant discovery related to Aventis's proposed claims of inequitable conduct will be conducted during the depositions of inventors and prosecuting attorneys of the '408 patent. Critically, all such depositions have already been timely noticed and either have gone forward or will go forward regardless of whether Aventis's proposed claims of inequitable conduct are added to the case. In sum, Novo fails to identify any prejudice that it would supposedly suffer from the grant of Aventis's Motion for Leave to Amend.

Moreover, Novo's unfair discovery tactics led to any purported delay by Aventis in filing its proposed claims of inequitable conduct. Aventis's claims arise from the prosecution of a patent application related to the patent-in-suit – an application that Novo misleadingly failed to identify to Aventis. In particular, on February 27, 2006, Aventis served Novo with a First Set of Requests for Production of Documents and Things that included multiple requests directed to patents and applications that are related to (or contain the same disclosure as) the patent-in-suit.³ Novo objected to such requests and refused to produce much of the requested information, including information on the clearly relevant U.S. Patent No. 6,562,011 (“the '011 patent”), which forms the basis of Aventis's proposed claims of inequitable conduct.⁴ Had Novo produced information on the '011 patent when requested, Aventis would have been able to plead its claims of inequitable conduct before the deadline of the Court's Scheduling Order.

Also, Novo makes multiple conclusory statements that it would suffer prejudice from the grant of Aventis's Motion for Leave to Amend, yet provides no specific reasons as to why that might

³ See Exhibit 1, Novo's Objections to Aventis's Production Request Nos. 43-47 (excerpt from Novo Nordisk's Responses to Aventis's First Set of Requests to the Plaintiff Novo Nordisk A/S for the Production of Documents and Things (Nos. 1-267)).

⁴ *Id.*

occur. Consequently, Novo has completely failed to meet its burden of showing that it would be unfairly disadvantaged by the new claims. Therefore, Aventis' Motion for Leave to Amend should be granted.

C. Aventis Has Timely Filed Its Motion for Leave to Amend

"The passage of time, without more, does not require that a motion to amend [an answer] be denied." *U.S. for Use and Ben. of B &R, Inc. v. Donald Lane Constr.*, 19 F. Supp.2d 217, 222 (D. Del. 1998) (citations omitted). Novo has failed to show anything "more"—such as undue delay or dilatory motives—on the part of Aventis that would justify denying the Motion for Leave to Amend.

1. The recently discovered evidence confirms that the Withheld References were material.

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⁵ See Aventis's Supporting Memorandum.

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Further,

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, Novo misreads and misapplies the *Inline* decision.

NOVO NORDISK A/S' ANSWERING BRIEF IN OPPOSITION TO AVENTIS'S MOTION FOR LEAVE TO FILE AN AMENDED ANSWER AND COUNTERCLAIMS ("Novo's Opposition") states that the *Inline* Court found a later-obtained deposition to be unnecessary and irrelevant to the defendants' proposed additional inequitable conduct claims.⁹ Actually, the *Inline* Court found the deposition testimony of an inventor of the patent-in-suit to be part of the "information necessary to properly plead the new inequitable conduct theories." *Inline*, 237 F.R.D. at 365-66 (defendants had all information necessary to assert their claims at the end of 2003, and the inventor's deposition was taken in June and July of 2003).

Again, more similar to the facts of the present case is *Enzo*, in which the pleadings were amended to include claims of inequitable conduct six months after the deadline of the Court's Scheduling Order. *Enzo*, 270 F. Supp.2d at 484-90. In this case, as in *Inline*, the Court found that depositions of two inventors were relevant and necessary to additional claims of inequitable conduct. *Id.*

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⁹ Novo's Opposition, pp. 15-16.

2. Aventis expeditiously filed its Motion for Leave to Amend after obtaining the necessary evidence to plead inequitable conduct with particularity.

Novo asserts that Aventis should have included these claims of inequitable conduct in its First Amended Answer because the Withheld References are publicly available patents.¹⁰ This, however, directly contradicts this Court's holding in *Enzo*. 270 F. Supp. 2d at 489 (holding that there was no undue delay in filing the claim even though the references were publicly available long before the filing of the motion for leave to amend). The fact that the Withheld References were publicly available is irrelevant to the Court's analysis of undue delay. What is relevant is that Novo failed to produce any information regarding the '011 patent in this litigation, public prior art references or otherwise. Such information would have revealed to Aventis the existence of the '011 patent and that would have shown that Novo knew of the "publicly available" Withheld References due to its prosecution of the '011 patent application.

Novo also claims that Aventis has unduly delayed filing these counts of inequitable conduct because Aventis was in possession of the '011 patent and file history on August 9, 2006, the date that it produced these documents to Novo. First, as stated in *Enzo*, Aventis was "prudent ... to confirm the factual allegations through discovery

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before pleading these counts of inequitable conduct. *Id.* at 489. Second, the '011 patent, a Novo patent, and its file history, were unearthed by Aventis in spite of Novo's refusal to comply with Aventis's discovery requests directed to just such related applications. Had Novo complied with the Federal Rules by producing the '011 patent and file history in response to Aventis's Production Request Nos. 43-47, Aventis would have discovered the relatedness of the '011 patent and the '408 patent much earlier.

¹⁰ Novo's Opposition pp. 3-4.

Further, once discovered, Aventis diligently reviewed these documents in preparation for the deposition of a prosecuting attorney for the patent-in-suit, Marc Began. During this review, Aventis discovered the newly asserted instances of inequitable conduct and properly confirmed these instances **REDACTED** Therefore, although Aventis was in possession of the '011 patent and file history prior to the date of its assertion of these claims of inequitable conduct, it was not aware of the substantial similarity of the subject matter of the '011 and the '408 patents, the fact that the same prosecuting attorneys were responsible for both patents, or the relevance of the Withheld References to the '408 patent **REDACTED**

Once Aventis confirmed these facts, it again acted diligently in carefully crafting very specific amendments to its counterclaims and a motion and memorandum seeking leave to file those very specific amendments.

Novo makes the unreasonable assertion that a period of one month between Mr. Began's testimony and the filing of Aventis's Motion for Leave to Amend constitutes undue delay. This contention is completely unsupported by the prior holdings of this Court. *See, e.g., Enzo*, 270 F. Supp. 2d 484. Of all the cases cited by Novo in which a motion for leave to amend was denied for undue delay, the shortest delay was *one and one-half years* from the time of possession of all the necessary information to make the claims. *Rose Hall, Ltd. V. Chase Manhattan Overseas Banking Corp.*, 93 F.R.D. 858 (D. Del. 1982) (delay of 2 years, 9 months); *M/V Am. Queen v. San Diego Marine Constr. Corp.*, 708 F.3d 1483 (9th Cir. 1983) (1½ years); *Lorenz*, 1 F.3d 1406 (at least 2 years); *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267 (3d Cir. 1989) (at least 1½ years). Finally, the case on which Novo so heavily relies as relevant to the present case involved a delay of over two years. *Inline Connection Corp.*, 237 F.R.D. 361 (delay of 2 years, 4

months). This argument, like the other unfounded arguments in Novo's Opposition, fails to provide the Court with any reason to deny Aventis's Motion for Leave to Amend.

II. NOVO'S ARGUMENTS ARE UNSUPPORTED BY THE FACTS

Many of the arguments raised in Novo's Opposition are irrelevant to the issue presently before this Court. Additionally, the facts do not support several of Novo's arguments and assertions. While a point-by-point refutation of Novo's arguments is unnecessary, Aventis takes this opportunity to correct the several of the erroneous conclusions that appear in Novo's Opposition. Briefly reiterated, the facts are these:

The '011 patent came to Aventis's attention after it conducted a search for prior art for the '408 patent. On August 7, 2006, Aventis produced to Novo, *inter alia*, the references it unearthed. While preparing for the deposition of Marc Began, Aventis discovered the substantial similarity of the specifications and subject matter of the '011 and the '408 patents. After discovering these marked similarities, Aventis intensely reviewed the file wrappers and the disclosed references in order to understand how the '011 patent related to the '408 patent.

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In light of this new evidence, and in an effort both to verify the merits of the claims of inequitable conduct and to plead with proper particularity in accordance with Fed. R. Civ. P. 9(b),

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Aventis worked diligently to draft the Second Amended Answer from the time of Mr. Began's deposition on October 3, 2006 until the filing of Aventis' Motion for Leave to Amend. Aventis gave notice of the Second Amended Answer to Novo on November 1, 2006, a week prior to filing the Motion for Leave to Amend on November 8, 2006.

A. Scheduling Issues

Novo uses previous deadline extensions to support the thin argument that Aventis is responsible for delaying these proceedings. In spite of its agreement to these extensions in front of this Court, Novo would now have the Court waste its time probing the reasons for those Joint Stipulations. Further, though the original date for the close of fact discovery as set forth in the Scheduling Order was October 19, 2006, Novo has made discovery requests and responses after the original deadline in accordance with the stipulated extensions. Previous deadline extensions were in the interests of both parties, and approved by this Court, and should not now be proffered as implicit evidence of a "pattern of delay" by Aventis.

B. The Merits of the Inequitable Conduct Claims Are Not Pertinent to This Motion

Novo's assertion that the '011 patent and the '408 patent are unrelated is belied by the facts as recited in the Second Amended Answer. Novo even goes so far as to imply that two patents are "not related" if those patents claim different matter.¹² However, in light of the statutory prohibition against double patenting, such a definition of "related" is nonsensical and would mean no two domestic patents are related to each other. Additionally, the relatedness debate is irrelevant to the legal standard of materiality; where two patents have substantially the same inventors, prosecuting attorneys, and specification, references material to one could very well be material to the other. In fact, Aventis does not solely rely on the relatedness of the two patents and asserts that, of the '011

¹² Novo's Opposition, p. 6.

references, only the Withheld References, with their critical inclusion of snapping components, rise to the level of materiality.

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Moreover, many of Novo's assertions are directed to the question of whether or not Novo attorneys or inventors committed inequitable conduct. This ultimate determination is not dispositive of the issue before the Court, as Aventis has shown here and in its Supporting Memorandum that the

¹³ Novo's Opposition, p. 6 (emphasis added).

¹⁴ Novo's Opposition, p. 7.

¹⁵ See Supporting Memorandum.

proposed amendments would not be futile.¹⁶ In the final analysis, Aventis has demonstrated good cause to justify the requested amendment, and Novo has failed to establish any prejudice that will result from the amendment.

III. CONCLUSION

In light of the foregoing, Aventis respectfully requests that the Court grant Aventis's Motion for Leave to Amend.

ASHBY & GEDDES

/s/ Lauren E. Maguire

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Dated: December 1, 2006

¹⁶ See, e.g., *Enzo*, 270 F. Supp.2d at 490 (Amendments were not futile when "the Court cannot conclude with certainty, at this juncture, that [defendants] can 'prove no set of facts in support of [its] claim which would entitle [it] to relief.'"), citing *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957).

EXHIBIT A

requests information regarding "Related Products" which as defined by Aventis is so overly broad that it renders this Request incomprehensible and not amenable to response.

REQUEST NO. 43

All documents and things that constitute the following patents and/or patent applications or that refer to, relate to, or constitute the preparation, filing, or prosecution of the following patents and/or patent applications, including draft applications:

(a) The patent-in-suit and all U.S. patents or patent applications (regardless of status) that claim priority from, contain the same disclosure as, have the same filing date as, incorporate by reference, or otherwise reference the patent-in-suit (including the application leading to the patent-in-suit itself); and

(b) All foreign patents or patent applications that contain the same disclosure as, rely for priority on, or are counterparts to any of the patents and patent applications identified in (a).

RESPONSE

In addition to its General Objections, Novo Nordisk objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and harassing in that it seeks categories of documents that are not relevant to or likely to lead to the discovery of admissible information relating to the claims and defenses asserted in this litigation. Novo Nordisk also objects to this Request in that it calls for production of information protected by the attorney-client privilege and work product immunity.

Subject to and without waiving its General and Specific Objections, Novo Nordisk will produce relevant, non-privileged documents constituting and concerning the patent-in-suit, any U.S. applications that led to the patent-in-suit or any foreign application to which the patent-in-suit claims priority to the extent that Novo Nordisk has custody and/or control over such documents and to the extent that such documents are located by a reasonable search.

REQUEST NO. 44

All documents and things that constitute the following patents and patent applications or that refer to, relate to, or constitute the preparation, filing, or prosecution of the following patents and patent applications, including draft applications:

(a) All foreign and U.S. patents and patent applications (regardless of status) that the patent-in-suit claims priority to, incorporates by reference, or otherwise references; and

(b) All foreign patents and patent applications that contain the same disclosure as, or rely for priority on, or are counterparts to any of the patents and patent applications identified in (a).

RESPONSE

In addition to its General Objections, Novo Nordisk objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and harassing in that it seeks categories of documents that are not relevant to or likely to lead to the discovery of admissible information relating to the claims and defenses asserted in this litigation. Novo Nordisk also objects to this Request in that it calls for production of information protected by the attorney-client privilege and work product immunity. Novo Nordisk also objects to this Request in that "counterparts" is undefined and thus its intended meaning is unclear. Novo Nordisk also objects to this Request as unduly burdensome and harassing in that is duplicative of other Aventis requests. Novo Nordisk also objects to this Request in that it calls for production of information protected by the attorney-client privilege and work product immunity.

Subject to and without waiving its General and Specific Objections, Novo Nordisk will produce relevant, non-privileged documents constituting and concerning the patent-in-suit, any U.S. applications that led to the patent-in-suit or any foreign application to which the patent-in-suit claims priority to the extent that Novo Nordisk has custody and/or control over such documents and to the extent that such documents are located by a reasonable search.

REQUEST NO. 45

All prior art cited by Novo in the respective patent office regarding any of the patents or patent applications identified in Request Nos. 43 and 44.

RESPONSE

In addition to its General Objections, Novo Nordisk objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and harassing in that it seeks categories of

documents that are not relevant to or likely to lead to the discovery of admissible information relating to the claims and defenses asserted in this litigation. Novo Nordisk also objects to this Request as vague and ambiguous, overly broad and unduly burdensome in that the term “prior art” is undefined. Novo Nordisk also objects to this Request as unduly burdensome in that it requests production of public documents which are equally available to Aventis as to Novo Nordisk.

Subject to and without waiving its General and Specific Objections, Novo Nordisk will produce relevant, non-privileged documents responsive to this Request concerning the patent-in-suit, any U.S. applications that led to the patent-in-suit or any foreign application to which the patent-in-suit claims priority to the extent that Novo Nordisk has custody and/or control over such documents and to the extent that such documents are located by a reasonable search.

REQUEST NO. 46

All records of invention, conception records, invention disclosure documents, or any other documentation or things setting forth, evidencing, referring to, or relating to the conception, discovery, or development of the subject matter disclosed and/or claimed in any of the patents or patent applications identified in Request Nos. 43 and 44.

RESPONSE

In addition to its General Objections, Novo Nordisk objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and harassing in that it seeks categories of documents that are not relevant to or likely to lead to the discovery of admissible information relating to the claims and defenses asserted in this litigation. Novo Nordisk also objects to this Request as vague and ambiguous in that it requests documents relating to the subject matter “disclosed” and “claimed” in patents that are not the subject of this litigation. Novo Nordisk also objects to this as overly broad, unduly burdensome, vague and ambiguous and not reasonably

calculated to lead to the discovery of admissible information in that it requests information regarding unclaimed subject matter. Novo Nordisk also objects to this Request as duplicative of other Aventis requests. Novo Nordisk also objects to this Request in that it calls for production of information protected by the attorney-client privilege and work product immunity. Novo Nordisk also objects to this Request as duplicative of other Aventis requests, including at least Request Nos. 48 and 28.

Subject to and without waiving its General and Specific Objections, Novo Nordisk will produce relevant, non-privileged documents responsive to this Request concerning the inventions claimed in the asserted claims of the patent-in-suit to the extent that Novo Nordisk has custody and/or control over such documents and to the extent that such documents are located by a reasonable search.

REQUEST NO. 47

All materials prepared for sending to the respective patent office regarding any of the patents or patent applications identified in Request Nos. 43 and 44, papers sent to or received from the respective patent office regarding any of the patents or patent applications identified in Request Nos. 43 and 44, notes and memoranda of interviews (telephonic or in person) with personnel from each respective patent office regarding any of the patents or patent applications identified in Request Nos. 43 and 44, and all communications with outside counsel that refer or relate to the preparation and prosecution of the any of the patents or patent applications identified in Request Nos. 43 and 44.

RESPONSE

In addition to its General Objections, Novo Nordisk objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and harassing in that it seeks categories of documents that are not relevant to or likely to lead to the discovery of admissible information relating to the claims and defenses asserted in this litigation. Novo Nordisk also objects to this Request in that it calls for production of information protected by the attorney-client privilege and work product immunity.

Subject to and without waiving its General and Specific Objections, Novo Nordisk will produce relevant, non-privileged documents responsive to this Request concerning the patent-in-suit and any U.S. applications that led to the patent-in-suit to the extent that Novo Nordisk has custody and/or control over such documents and to the extent that such documents are located by a reasonable search.

REQUEST NO. 48

All documents and things that evidence, refer to, relate to, or constitute the research or development that led to or that resulted in the subject matter disclosed and/or claimed in any of the patents or patent applications identified in Request Nos. 43 and 44.

RESPONSE

In addition to its General Objections, Novo Nordisk objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and harassing in that it seeks categories of documents that are not relevant to or likely to lead to the discovery of admissible information relating to the claims and defenses asserted in this litigation. Novo Nordisk also objects to this Request as vague and ambiguous in that it requests documents relating to the subject matter “disclosed” and “claimed” in patents that are not the subject of this litigation. Novo Nordisk also objects to this as overly broad, unduly burdensome, vague and ambiguous and not reasonably calculated to lead to the discovery of admissible information in that it requests information regarding unclaimed subject matter. Novo Nordisk also objects to this Request as duplicative of other Aventis requests, including at least Request Nos. 46 and 28. Novo Nordisk also objects to this Request in that it calls for production of information protected by the attorney-client privilege and work product immunity.

Subject to and without waiving its General and Specific Objections, Novo Nordisk will produce relevant, non-privileged documents responsive to this Request concerning the inventions claimed in the asserted claims of the patent-in-suit to the extent that Novo Nordisk

CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of December, 2006, the attached **REDACTED**
PUBLIC VERSION OF AVENTIS'S REPLY BRIEF IN RESPONSE TO NOVO
NORDISK A/S' ANSWERING BRIEF IN OPPOSITION TO AVENTIS'S MOTION FOR
LEAVE TO FILE AN AMENDED ANSWER AND COUNTERCLAIMS was served upon
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